

**IN THE UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

DAWN TUCKER, et al.,

Plaintiffs,

v.

ETHICON, INC. and
JOHNSON & JOHNSON,

Defendants.

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Case No. 4:20-cv-01543-RLW

DEFENDANTS' TRIAL BRIEF

Defendants Ethicon, Inc. and Johnson & Johnson (collectively “Ethicon” or “Defendants”) respectfully submit this Trial Brief regarding key legal issues to be addressed at trial. The below sets forth the facts and procedural history of this case, as well as the standards by which Plaintiffs’ claims should be evaluated at trial. Defendants do not anticipate any substantive or procedural problems in this trial at this time.

I. Statement of the Case

Plaintiff Dawn Tucker asserts claims arising out of her TVT-Secur implant, which is a prescription medical device manufactured and sold by Ethicon. She was implanted with the TVT-Secur mesh product on November 15, 2011, to treat her stress urinary incontinence. Mrs. Tucker is now 55-years-old and claims that the TVT-Secur was defective and caused her alleged injuries. Defendants deny Plaintiffs’ allegations.

A. The TVT-Secur

Stress urinary incontinence (“SUI”) is the unintentional loss of urine when physical activity or movement associated with everyday activities (coughing, sneezing, running or heavy lifting) puts pressure or “stress” on the bladder. Synthetic mesh midurethral slings (MUS) are recognized

and recommended as the first line, suitable, safe, and effective surgical option for SUI. Compared with the prior surgical options used to treat SUI, MUS procedures (1) are more easily taught and performed; (2) are less invasive, requiring less dissection and much smaller incisions; (3) have a shorter recovery time; (4) have high levels of long-term efficacy; (5) cause less surgical pain; and (6) cause fewer complications overall.

TVT-Secur, which is categorized as a “mini” sling (about 3 inches long), has been shown to be safe and effective, although some studies demonstrated lower rates of efficacy compared to full-length slings. The lower rates of efficacy were most likely due to the surgeon learning curve in using the product. Even still, the benefits of TVT-Secur far outweigh the risks, but there are risks – just as there are risks with every surgical procedure. Those risks, including mesh exposure, are well-known and documented in the medical community. Many of the same complications that can occur with mesh slings also occur with non-mesh slings – and mesh slings have far better long-term success rates.

In January 2012, the FDA directed all manufacturers of transvaginal mesh devices to conduct post-market surveillance studies to further assess the risk of complications with certain of those devices. TVT-Secur was among them. Due to the costs associated with such post-market surveillance and the product’s declining sales, Ethicon made a business decision to discontinue the sale of the TVT-Secur in June 2012.

B. Ms. Tucker’s Medical History and Lawsuit

i. Pre-Implant Medical History

Mrs. Tucker had a complex medical history before her 2011 TVT-Secur placement. She required a number of surgical and non-surgical interventions related to her reproductive organs and lower abdominal/pelvic muscles. Specifically, she had a surgical repair of a bilateral inguinal

hernia, dilation and curettage (“D&C”) to remove tissue from inside the uterus, a caesarian section, and the D&C of an endometrial ablation, which was a different procedure to remove the lining of the uterus. Her medical history included numerous documented instances of a right adnexal cyst, menorrhagia, dysmenorrhea, probable uterine adenomyosis (a condition where the tissue that lines the uterus invades the uterine wall), and stress urinary incontinence. She also has a documented history of obesity, both before and after her mesh implant, which is an established risk factor that can contribute to post-operative complications.

ii. SUI and 2011 TVT-Secur Placement

As some point after the birth of her two children, Mrs. Tucker began to experience SUI, where she leaked urine when she coughed, laughed, and with physical activity, particularly exercise. She also experienced urge incontinence, which involved urinary leakage following a sudden urge to urinate. Mrs. Tucker wore a pad, which she changed once a day, and has acknowledged there were times when her incontinence interfered with her work and quality of life.

In October 2011, Mrs. Tucker reported heavy vaginal bleeding, increasing pain with periods, and stress and urge-related urinary incontinence to her gynecologist, Dr. Jack Ricketts. Because Mrs. Tucker had failed more conservative therapies, Dr. Ricketts recommended a hysterectomy, as well as a TVT-Secur sling to treat SUI.

Dr. Ricketts believed that he read the Instructions for Use (“IFU”) for the TVT-Secur when he was learning to perform the surgery to place the device, but also relied upon his education, training, and experiences as a gynecological surgeon when recommending it to Mrs. Tucker. He was independently aware that recurrence of incontinence, device failure, and erosion or exposure were risks of TVT-Secur surgery. Dr. Ricketts chose to use the TVT-Secur because he believed this sling was more beneficial for patients as it required fewer incisions to place than other devices

or procedures. Dr. Ricketts had been using the TVT-Secur in his practice since 2007. He also had nearly a decade of experience using other mid-urethral slings manufactured by Ethicon.

Mrs. Tucker wished to proceed with surgery. On November 15, 2011, Dr. Ricketts performed a diagnostic laparoscopy and laparoscopic-assisted vaginal hysterectomy that included the removal of both ovaries and both fallopian tubes. He also implanted the TVT-Secur sling.

iii. Subsequent Procedures and Medical Care

On March 19, 2012, Mrs. Tucker saw Dr. Ricketts due to painful intercourse. She also was losing urine. Mrs. Tucker returned to Dr. Ricketts in August 2012 with complaints of suprapubic pain and painful intercourse. Dr. Ricketts suspected possible mesh exposure and scheduled a vaginal exploration with potential removal of the sling. On October 26, 2012, Dr. Ricketts performed the vaginal exploration procedure, removed a portion of the TVT-Secur, and removed abdominal adhesions. On November 9, 2012, Ms. Tucker reported pelvic pain to Dr. Ricketts, but he found no vaginal abnormalities during his examination and documented that she was progressing as expected. Mrs. Tucker last saw Dr. Ricketts in December 2012.

Mrs. Tucker claims her incontinence and pelvic pain continued as the years elapsed, although she did not seek medical treatment for them again until August 2015. On August 13, 2015, she consulted Dr. Dionysios Veronikis, who is an established plaintiff expert in the pelvic mesh litigation. She complained of urinary incontinence dating back to 2009, urinary frequency and urgency, pelvic pain, and pain with intercourse. Dr. Veronikis performed a diagnostic procedure that did not demonstrate SUI and produced no evidence of detrusor instability. He also noted a stable bladder neck. Dr. Veronikis discussed the option of surgery to remove additional portions of the TVT-Secur and counseled Mrs. Tucker that the procedure provided no guarantee to relieve her pain. Mrs. Tucker wished to proceed with the surgery.

On September 25, 2015, Dr. Veronikis performed a sling removal, removal of mesh anchor from obturator internus muscle, and urethrolisis. His operative report indicated a urethral erosion, which is a complication associated with slings at an incredibly low rate, characterized in medical literature as “rare.” Mrs. Tucker saw Dr. Veronikis for a post-operative visit on November 5, 2015. She was doing well and advised to follow up depending on her incontinence status.

More than three years passed before Mrs. Tucker saw Dr. Veronikis again. On May 16, 2019, she reported pain with intercourse with initial penetration. Dr. Veronikis discussed surgery, including colpoperineorrhaphy, which Dr. Veronikis explained involved removing a skin bridge (that was unrelated to the TVT-Secur) to assist with this pain. Mrs. Tucker wished to proceed. She has testified this surgery was cancelled after she fractured a rib. It was not rescheduled. On July 29, 2019, Mrs. Tucker returned to Dr. Veronikis for vaginal pain. Following an examination, Dr. Veronikis’s new impression was that surgery would not resolve her pain. He instead suggested urodynamic evaluation. Mrs. Tucker did not return to Dr. Veronikis. Nor has she undergone any further vaginal surgeries.

Mrs. Tucker has testified that she has one or two urinary tract infections per year since her TVT-Secure was placed. However, her medical records contain a paucity of information about urinary tract infections. In addition, Ethicon is unaware of Mrs. Tucker receiving any medical treatment for her alleged injuries following her last visit with Dr. Veronikis in 2019. Her medical records reflect a focus on treatment for orthopedic issues, as well as document obesity, through 2020.

iv. Plaintiffs’ Lawsuit

Plaintiffs filed suit in the Ethicon MDL on September 23, 2016. After summary judgment briefing and the Court’s ruling, Plaintiffs’ remaining claims are: negligence and strict liability (to

the extent each cause of action is based on a theory of design defect and/or failure to warn), common law fraud, fraudulent concealment, negligent misrepresentation, violation of the Missouri's Manufacturing Practices Act, Recklessness, Loss of Consortium, and Punitive Damages.

II. Claims and Legal Standards

A. Design Defect

Plaintiffs asserts a claim, in strict liability and in negligence, that the TVT-Secur was defective in design.¹ To establish such a claim, Plaintiffs must show: (1) that the TVT-Secur's design was defective, and (2) that the defect caused Ms. Tucker's injury. *Pritchett v. Cottrell, Inc.*, 512 F.3d 1057, 1063 (8th Cir. 2008) (citing *Richcreek v. Gen. Motors Corp.*, 908 S.W.2d 772, 776 (Mo. Ct. App. 1995)). "The 'heart and soul' of a strict liability design defect case is unreasonable danger and causation." *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo. Ct. App. 2008) (quoting *Nesselrode v. Exec. Beechcraft, Inc.*, 707 S.W.2d 371, 376 (Mo. 1986)). "A plaintiff proves causation in a product defect case 'by providing competent expert testimony or additional evidence that the defendant's product was a substantial factor in causing the injury.'" *Mathes v. Sher Express, LLC*, 200 S.W.3d 97, 103 (Mo. Ct. App. 2006) (quoting *Dorman v. Bridgestone/Firestone, Inc.*, 992 S.W.2d 231, 237 (Mo. Ct. App. 1999)).

Plaintiffs must prove that a demonstrated defect in the TVT-Secur caused her injuries, not just that the device generally did. *Abt v. Ethicon, Inc.*, 1:20-CV-0047 SRC, 2020 WL 4887022, at *3–4 (E.D. Mo. Aug. 20, 2020); *see also Richcreek*, 908 S.W.2d at 776 (To establish liability, a

¹ Although the Missouri Supreme Court has held "that negligence and strict liability theories of product liability are separate and distinct theories. Finding against the plaintiff on a strict liability product defect theory does not require rejection of plaintiff's claims of negligent design, manufacturing, or failure to warn," here the foundation of Plaintiff's negligence claims are identical to her strict liability claims and she cannot prevail on either. *See Johnson v. Auto Handling Corp.*, 523 S.W.3d 452, 466 (Mo. 2017).

plaintiff must show the product is defective, as designed, and that the “demonstrated defect caused his injuries.”); *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo. Ct. App. 2008) (same); *see also Lewis v. Johnson & Johnson*, 601 Fed. App'x 205, 211 (4th Cir. 2015) (affirming directed verdict for defendants where expert testified the presence of the TVT caused plaintiff's pain but did not testify that a defect in the TVT caused her pain).

Plaintiffs are unable to prove that the TVT-Secur was defective or that any such defect caused Ms. Tucker's injuries.

B. Failure to Warn

Plaintiffs also assert a claim for strict liability and negligent failure to warn. To establish a failure to warn claim, Plaintiffs must establish: “(1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning.” *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011).

Missouri courts apply the learned intermediary doctrine to failure to warn claims involving prescription drugs or medical devices. *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999); *Kirsch v. Picker Intern., Inc.*, 753 F.2d 670, 671 (8th Cir. 1985) (applying Missouri law). Under the learned intermediary doctrine, “a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products.” *Doe*, 3 S.W.3d at 419. “[A]ny warning given to the physician is deemed a warning to the patient.” *Id.* To establish causation under the learned intermediary doctrine, Plaintiffs must show that “additional warnings would have altered the behavior of her physician” and avoided the

injury. *Abt v. Ethicon, Inc.*, 1:20-CV-0047 SRC, 2020 WL 4887022, at *2–3 (E.D. Mo. Aug. 20, 2020). There is no duty to warn of risks that are commonly known among pelvic floor surgeons. *Young v. Wadsworth*, 916 S.W.2d 877, 878 (Mo. App. E.D. 1996) (“There is no duty or need to warn of dangers which are open and obvious or which are commonly known.”); *Grady v. American Optical Corp.*, 702 S.W.2d 911, 915 (Mo. App. E.D. 1985) (“manufacturers and distributors are not under a duty to provide warnings about dangers which are open and obvious, or which are commonly known.”).

Defendants provided an adequate warning of the risks of the TVT-Secur in light of the common knowledge of pelvic floor surgeons, and Plaintiffs cannot establish that any purported inadequacy in the TVT-Secur warning caused her alleged injuries here.

C. Fraudulent and Negligent Misrepresentation

To establish a claim for fraudulent misrepresentation under Missouri law, Plaintiffs must show “(1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) the speaker's intent that it should be acted on by the person and in the manner reasonably contemplated; (6) the hearer's ignorance of the falsity of the representation; (7) the hearer's reliance on the representation being true; (8) the hearer's right to rely thereon; and (9) the hearer's consequent and proximately caused injury.” *Hess v. Chase Manhattan Bank, USA, N.A.*, 220 S.W.3d 758, 765 (Mo. 2007) (en banc)). For a claim of fraudulent nondisclosure, the first element—the existence of a representation—can be established with evidence of a party's silence in the face of a legal duty to speak. *Id.*; *Tucker v. Ethicon, Inc.*, 4:20-CV-1543 RLW, 2021 WL 410058, at *7 (E.D. Mo. Feb. 5, 2021).

Similarly, the elements of a negligent misrepresentation claim are that “(1) the speaker supplied information in the course of his business; (2) because of the speaker's failure to exercise

reasonable care, the information was false; (3) the information was intentionally provided by the speaker for the guidance of limited persons in a particular business transaction; (4) the hearer justifiably relied on the information; and (5) due to the hearer's reliance on the information, the hearer suffered a pecuniary loss.” *Renaissance Leasing, LLC v. Vermeer Mfg. Co.*, 322 S.W.3d 112, 134 (Mo. 2010).

For the same reasons Plaintiffs cannot prevail on a claim for failure to warn, Plaintiffs cannot establish a claim for fraudulent or negligent misrepresentation.

D. Violation of Missouri Merchandising Practices Act

To establish a claim under the Missouri Merchandising Practices Act (“MMPA”), §§ 407.010–.130, Mo. Rev. Stat., Plaintiff must establish that she Plaintiff has “purchase[d] or lease[d] merchandise primarily for personal, family or household purposes and thereby suffers an ascertainable loss...as a result of the use or employment” of a prohibited act or practice. § 407.025 Mo. Rev. Stat.; *Fabas Consulting Int'l, Inc. v. Jet Midwest, Inc.*, 74 F.Supp.3d 1026, 1030 n.4 (W.D. Mo. 2015). The “MMPA prohibits ‘deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce’ by defining such activity as an unlawful practice.” *Plubell v. Merck & Co., Inc.*, 289 S.W.3d 707, 711 (Mo. Ct. App. 2009) (quoting § 407.020.1).

For the same reasons Plaintiffs cannot prevail on a claim for failure to warn, Plaintiffs cannot establish a claim under the Missouri Merchandising Practices Act.

E. Recklessness

A tort for recklessness requires proof of an even greater level of culpable conduct. As the Missouri Supreme Court has explained:

Negligence is one kind of tort, an unintentional injury usually predicated upon failure to observe a prescribed standard of care (52 Am.Jur., Sec. 20) while a willful, wanton, reckless injury is another kind of tort, an intentional injury often based upon an act done in utter disregard of the consequences. 52 Am.Jur., Secs. 22, 23; 38 Am.Jur., Secs. 4, 5. Reckless conduct may be negligent in that it is unreasonable but it is and must be something more than unreasonable, “it must contain a risk of harm to others in excess of that necessary to make the conduct unreasonable and therefore, negligent.” 2 Restatement, Torts, p. 1294. “The actor's (defendant's) conduct is in reckless disregard of the safety of another if he intentionally does an act or fails to do an act which it is his duty to the other to do, knowing or having reason to know of facts which would lead a reasonable man to realize that the actor's conduct not only creates an unreasonable risk of bodily harm to the other but also involves a high degree of probability that substantial harm will result to him.” 2 Restatement, Torts, Secs. 500, 501.

Nichols v. Bresnahan, 212 S.W.2d 570, 573 (Mo. 1948), *quoted in Tucker v. Ethicon, Inc.*, 4:20-CV-1543 RLW, 2021 WL 410058, at *10–11 (E.D. Mo. Feb. 5, 2021).

Just as Plaintiffs cannot establish a claim for strict liability, they cannot establish a claim for recklessness, which requires proof of a higher degree of culpability.

F. Loss of Consortium

“Missouri has consistently followed the well-established rule that the plaintiff's right to recover for loss of consortium of her spouse is derivative only, so that if the spouse has no valid claim for personal injuries, the plaintiff cannot recover special damages flowing there from.” *Dille v. Renaissance Hotel Mgt. Co., LLC*, 4:10CV1983 TIA, 2012 WL 2396666, at *5 (E.D. Mo. June 25, 2012) (citing *Wright v. Barr*, 62 S.W.3d 509, 537 (Mo. Ct.App. 2001)). Because Ms. Tucker’s substantive claims are without merit, Mr. Tucker’s claims fail as well.

G. Punitive Damages

Plaintiffs cannot establish a claim for punitive damages because their substantive claims fail. Alternatively, they cannot establish the standards for punitive damages set forth in New Jersey law, which applies here to this issue. Punitive damages are an extreme remedy, and “are not to be applied in the ordinary unaggravated tort case whether it be grounded on strict liability or fault.”

Fischer v. Johns-Manville Corps., 472 A.2d 577, 582 (N.J. Super App. Civ. 1984) (quotation omitted). They cannot be awarded for negligence, even gross negligence. *Pavlova v. Mint Management Corp.*, 868 A.2d 322, 326 (N.J. Super Ct. App. Div. 2005) (“mere negligence, however gross, is not enough”); N.J. Stat Ann. § 2A:15-5.12 (“This burden of proof may not be satisfied by proof of *any* degree of negligence including gross negligence.” (emphasis added)). And they require the plaintiff to prove “something more” than the underlying tort. *Berg v. Reaction Motors Div., Thiokol Chemical Corp.*, 181 A.2d 487, 496 (N.J. 1962) (quotation omitted); *Edwards v. Our Lady of Lurdes Hosp.*, 526 A.2d 242, 249 (N.J. App. Div. 1987) (Plaintiff may not “rely[] on the same evidence to establish negligence and the elements for punitive damages.”).

That “something more,” the law makes clear, is outrageous conduct guided by evil intent—that is, “[t]here must be an intentional wrongdoing in the sense of an ‘evil-minded act,’” *Nappe v. Anschelewitz, Barr, Ansell & Bonello*, 477 A.2d 1224, 1230 (N.J. 1984), or a “conscious and deliberate disregard of the interests of others” so aggravated “that the tortfeasor’s conduct may be called wanton and willful,” *Dong v. Alape*, 824 A.2d 251, 257 (N.J. App. Div. 2003); *see also* N.J. Stat. Ann. § 2A:15-5.10. The requisite evil intent must be established by “clear and convincing evidence”—*i.e.*, “evidence so clear, direct and weighty and convincing as to enable [the factfinder] to come to a clear conviction, without hesitancy.” *Matter of Jobes*, 529 A.2d 434, 441 (N.J. 1987).

The evidence shows that in developing TVT-Secur Ethicon acted in good faith to provide a product to help women suffering from the serious and often life-altering condition of stress urinary incontinence. Plaintiffs cannot establish, by clear and convincing evidence, an intentional and evil act or reckless disregard accompanied by deliberate indifference.

III. Conclusion.

The evidence at trial will show that Ethicon acted reasonably in designing the TVT-Secur and formulating its warnings; that the warnings and design were not defective; and that Plaintiffs are unable to establish any defect in the TVT-Secur design or warnings caused Mrs. Tucker's alleged injuries. Plaintiffs further cannot show that Mrs. Tucker's injuries were caused by the TVT-Secur and not an alternative cause. For the same reasons, Plaintiffs also cannot establish a claim for fraud, fraudulent concealment, negligent misrepresentation, violation of the Missouri Manufacturing Practices Act, negligence, recklessness, or loss of consortium.

Finally, even if Plaintiffs are able to establish a claim for relief, they are not entitled to punitive damages. Ethicon acted at all times in good faith to create a better, safer product to improve women's health, and Plaintiffs cannot show Ethicon's actions were intentional, malicious, willful, wanton, or made with conscious or deliberate indifference to the consequences or made with an entire want of care.

Accordingly, Defendants are entitled to judgment on all claims.

Dated: October 12, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 12th day of October, 2021, a true and correct copy of the foregoing instrument was electronically filed with the Clerk of Court and served to all counsel of record via the Court's CM/ECF system.

/s/ Cicely I. Lubben

Attorney for Defendants Ethicon, Inc. and
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